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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,499

Applicant(s)

SUROLIA, NAMITA

Examiner

Kevin E. Weddington

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-13, 15, 16, 19, 20 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-13, 15, 16 and 36-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 7-13, 15, 16, 19, 20 and 36-50 are presented for examination.

Applicant's election filed August 8, 2004 in response to the restriction requirement of July 16, 2004 has been received and entered. The applicant elected the invention described in claims 7, 9-16 and 43 (Group I) with traverse.

Applicant's traverse of the restriction requirement is deemed in-part that the claims 7-13, 15, 16 and 36-50 will be examined together, but claims 19 and 20 (Group III) are a distinct and separate invention.

Claims 19 and 20 are withdrawn from as being drawn to the non-elected invention (37 CFR 1.142(b)).

Title

Applicant may wish to change the word "GLASS" to "CLASS" in the Title.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9-13 and 36-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for triclosan [5-chloro-2-(2,4-dichlorophenoxy)phenol], does not reasonably provide enablement for other inhibitors of fatty acid synthesis, such as other hydroxydiphenyl ether of general formula 2 wherein the X is S and CH₂. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

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The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to an antimalarial composition comprising an inhibitor of fatty acid synthesis.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The prior art, Surolia et al., "Triclosan offers protection against blood stages of malaria by inhibiting enoyl-ACP reductase of Plasmodium falciparum", Nature Medicine (Feb. 2001), Vol. 7 (2). Pages 167-173; shows only triclosan possesses antimalarial activity.

It is clear the art to which the present invention relates is highly unpredictable and unreliable for the other inhibitors of fatty acid synthesis, such as other hydroxydiphenyl ethers of general formula 2 wherein the X is S and CH₂ with respect to conclusions drawn from the laboratory data.

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The breadth of the claims

The claims are very broad and inclusive of any inhibitor of fatty acid synthesis.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of triclosan.

The quantity of experimentation necessary

Applicant has failed to provide guidance the other inhibitors of fatty acid synthesis, including other hydroxydiphenyl ethers of general formula 2 wherein X is S and CH₂. The instant specification sets forth no such understanding nor any criteria for using other inhibitors of fatty acid synthesis beyond triclosan. The level of experimentation needed to determine the other inhibitors of fatty acid synthesis possessing antimalarial activity is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 7, 9-13 and 36-42 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is rendered indefinite and vague because there is no definition for X.

Claim 42 is not allowed.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dick et al.

(5,614,551).

Dick et al. teach inhibitors of fatty acid synthesis as antimicrobial agents (See the abstract). Note particularly column 3, lines 36-41 states the Type I FAS (fatty acid synthesis inhibitor), cerulenin, is effective against intercellular parasites or protozoa, such as *Toxoplasma gondii*. Column 12, lines 24-40 show the FAS inhibitors are formulated into pharmaceutical compositions (same applicant's claim 1). Column 12, lines 41-43 shows an amount effective to treat the infection caused by the parasite. Note applicant's claims read on the compound and the intended use limitation for treatment of malaria does not affect nor alter the function of the composition nor the components thereof. Clearly, the cited reference anticipates every limitation of applicant's claims 7 and 16; therefore, the instant invention is unpatentable.

Claims 7 and 16 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dick et al. (5,614,551).

Dick et al. were discussed above supra for the compositions containing inhibitors of fatty acid synthesis, especially cerulenin.

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The instant invention differs from the cited reference in that the cited reference does not each the dosage range of the fatty acid synthesis inhibitor of claim 15. However, to determine a dosage having optimum effectiveness against malaria is well within the level of one having ordinary skill in the art, and the skilled artisan would have been motivated to determine optimum amounts to get the maximum effectiveness in the absence of evidence to the contrary.

Claim 15 is not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9 and 43-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dick et al. (5,614,551) or Model et al. (3,629,477) in view of Windholz et al. (THE MERCK INDEX, Tenth Edition, 1983, pages 304-305, abstract no. 2136.

Dick et al. teach inhibitors of fatty acid synthesis, such as cerulenin, are effective against bacteria and protozoa (See column 3, lines 36-41).

Model et al. teach halogenated diphenylether-containing compositions wherein the halogenated diphenylether compound is 4,2'4'-trichloro-2-hydroxy-diphenyl ether (triclosan), applicant's preferred inhibitor of fatty acid synthesis of claim 9 and 45. Note the halogenated diphenylethers are effective in combating bacteria (See claims 10-15 of the Model et al.).

The instant invention differs from the cited references (both individually) in that the cited references do not teach the addition of a known antimalarial compound with the inhibitors of fatty acid

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synthesis. The secondary reference, Windholz et al., teach one of the applicant's preferred antimalarial compound, chloroquine, is cited to show the state of the art. One skilled in the art would have assumed the combination of a fatty acid synthesis inhibitor, such as cerulenin with chloroquine into a single composition would give an additive effect since cerulenin is effective against protozoa and chloroquine is effective against malaria (caused by a protozoa) in the absence of evidence to the contrary. One skilled in the art would have assumed the combination of triclosan and chloroquine into a single composition would give an additive effect in the absence of evidence to the contrary.

The instant invention differs from the cited references in that the cited references do not teach the triclosan (an antibacterial agent) would be effective against malaria (caused by a protozoa). However, one skilled in the art would have assumed the antibacterial properties would be effective against any microorganisms that are harmful to the infected host, thus the properties (antibacterial activity) would be effective against protozoa (a microorganism) in the absence of evidence to the contrary.

Claims 8, 9 and 43-49 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Model et al. (3,629,477) in view of Dick et al. (5,614,551).

Model et al. teach halogenated diphenylether compounds, such as triclosan, are possessing antibacterial activity.

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The instant invention differs from the cited reference in that the cited reference does not teach the addition of a second agent, cerulenin with triclosan. However, the secondary reference, Dick et al., teaches cerulenin as having antibacterial activity also. Clearly, one skilled in the art would have assumed the combination of two individually well-known antibacterial agents into a single composition would give an additive effect in the absence of evidence to the contrary.

Claim 50 is not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
December 28, 2004